

REMARKS

Status of the Application

Claims 1-12 remain pending in the present application. Support for the amendment to Claim 1 is found at page 5, line 15 to page 6, line 7. Accordingly, no new matter is incorporated by this Amendment.

Rejections under 35 U.S.C. § 102

The Office Action rejects Claims 1-3, 5-7, and 9-12 under 35 U.S.C. § 102(e) as purportedly anticipated by Majeed et al, U.S. Patent No. 6,436,991.

The Office Action rejects Claim 8 under 35 U.S.C. § 102(e) as purportedly anticipated by Majeed et al, U.S. Patent No. 6,436,991, in combination with Goodman and Gilman's: The Pharmacological Basis of Therapeutics, 9th Edition (1995), pp. 513-514.

Rejection under 35 U.S.C. § 103

The Office Action rejects Claim 4 under 35 U.S.C. § 103(a) as purportedly rendered unpatentable based on Majeed et al, U.S. Patent No. 6,436,991, in combination with Reilly Jr. Pharmaceutical Necessities, Remington: The Science and Practice of Pharmacy (1994), pp.1408-1414.

All claims are drawn, *inter alia*, to a method of treating a cognitive memory dysfunction in a mammal, said method comprising administering to said mammal a pharmaceutically acceptable composition consisting essentially of a memory enhancing effective amount of *gugulipid*. The rejections all rely upon Majeed et al to disclose *gugulipid* as present in all the claims. However, Majeed et al does not disclose *gugulipid* as claimed.

According to Applicant's invention, *gugulipid* is a product prepared by a method comprising extracting a resin from the aerial branches of the plant *C. wightii* and said resin is

extracted by a process comprising:

- a) suspending a gum or resin of the plant in a non-polar solvent;
- b) filtering or decanting the soluble portion;
- c) extracting a fatty acid;
- d) extracting the residue with ethyl acetate using shaking or sonication;
- e) mixing the polar and non-polar fractions;
- f) filtering to remove the solid suspension; and
- g) removing the solvent to obtain the *gugulipid*.

As such, the *gugulipid* is a specific extract with controlled proportions of components derived from the aerial branches of the plant *C. wightii*. In contrast, the Office Action states that the Majeed et al disclosure “does not disclose the instant steps reciting the process by which the *gugulipid*” in Majeed et al is obtained. See point 4, on page 3 of the Office Action.

The Office Action proceed to state that “these limitations are not afforded patentable weight in that the invention lies in the method of treatment...” Applicants submit this position is erroneous. The claims are drawn to a method requiring utilization of a specific extract product made by a particular process. Extracts are composed of a variety of components, the quality and quantity of each being controlled by the source material, and the process steps involved. In that the Majeed et al fails to teach what portion of the plant is extracted, or the particular extraction steps accessed, there is no basis on which to premise that the *gugulipid* of the present invention is anticipated by any product in Majeed et al. In addition, it is known that some of the individual components expressly differ in chemical structure. For instance, in Majeed et al the active compound identified is ferulate compound, while in the instant invention, the active compound is *gugulipid*. Accordingly, neither Majeed et al nor the secondary reference teach or suggest *gugulipid* according to the claimed invention, and this distinction passes through all the claims.

In addition, the disclosure of Majeed et al fails to meet the claim for additional reasons. Majeed et al, at column 4, lines 25-49, is limited to disclosing Alzheimer's disease, and no other forms of memory dysfunction. This limited reference is narrowed to considering Alzheimer's as an inflammatory disease, and not as a cognitive memory disorder. In addition, the functional dosages suggested for the active compounds in Majeed et al for the conditions in that disclosure are far lower than those claimed for the instant invention.

In addition Majeed et al is directed to the disclosure of ferulate compounds, not *gugulipid*. It is the ferulate compounds that Majeed et al teaches as the active agent for the treatment of various conditions. For the treatment of memory dysfunction, Majeed et al is directed to the use of these ferulate compounds and does not disclose the use of *gugulipid* for treating such an indication. See Majeed et al at column 4, lines 24-48.

For all the reasons above, reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants respectfully request withdrawal of the rejections. As the claims are otherwise in compliance with the requirements of Title 35, they are in condition for allowance, and notice of the same is respectfully requested. If any points remain in issue that the Examiner feels may

be best resolved through a personal or telephonic interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP

A handwritten signature in black ink, appearing to read 'S. Kelber', written over a horizontal line.

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